

TABLE 146

Female Sexual Function Index Total and Domain Scores:									
Category	Score	4 $\mu$ g		10 $\mu$ g		25 $\mu$ g		Placebo	
		Mean	SD	Mean	SD	Mean	SD	Mean	SD
Total	Baseline	14.8	6.13	15.8	6.24	14.2	6.21	14.4	6.61
	Week 12	22.6	8.4	24.8	7.59	24.8	7.59	22	8.54
	Change	7.98	7.551	8.85	7.361	10.49	8.176	7.74	8.41
	LS Mean	7.909	0.9075	9.431	0.0492	10.283	0.0019	7.458	—
Arousal	Baseline	2.8	1.44	2.9	1.43	2.7	1.5	2.7	1.41
	Week 12	3.6	1.61	4.1	1.47	4.1	1.39	3.6	1.52
	Change	0.88	1.615	1.16	1.632	1.43	1.646	1.02	1.607
	LS Mean	0.876	0.9777	1.288	0.0581	1.393	0.008	0.927	—
Desire	Baseline	2.6	1.01	2.7	1.13	2.6	1.09	2.7	1.07
	Week 12	3.3	1.11	3.5	1.13	3.5	1.06	3.3	1.21
	Change	0.64	1.065	0.78	1.113	0.87	1.105	0.62	1.102
	LS Mean	0.626	1	0.801	0.2753	0.849	0.1139	0.628	—
Lubrication	Baseline	2.1	1.25	2.3	1.25	2	1.19	2	1.29
	Week 12	3.9	1.84	4.4	1.56	4.3	1.65	3.6	1.77
	Change	1.84	1.782	2.12	1.612	2.36	1.744	1.64	1.871
	LS Mean	1.835	0.4023	2.243	0.0012	2.3	0.0003	1.591	—
Orgasm	Baseline	2.7	1.74	2.9	1.74	2.4	1.68	2.4	1.73
	Week 12	3.8	1.89	4.1	1.75	4.1	1.66	3.7	1.97
	Change	1.12	1.93	1.09	1.821	1.68	1.857	1.31	1.86
	LS Mean	1.162	0.9978	1.273	0.9424	1.59	0.0763	1.189	—
Satisfaction	Baseline	2.9	1.37	3.2	1.43	2.9	1.37	2.9	1.49
	Week 12	4.2	1.54	4.4	1.37	4.6	1.35	4.1	1.55
	Change	1.31	1.512	1.24	1.534	1.64	1.613	1.23	1.661
	LS Mean	1.256	0.8798	1.382	0.3484	1.628	0.0063	1.165	—

While the pharmaceutical compositions and methods have been described in terms of what are presently considered to be practical and preferred embodiments, it is to be understood that the disclosure need not be limited to the disclosed embodiments. It is intended to cover various modifications and similar arrangements included within the spirit and scope of the claims, the scope of which should be accorded the broadest interpretation so as to encompass all such modifications and similar embodiments. This disclosure includes any and all embodiments of the following claims.

What is claimed is:

1. A method for treating moderate to severe dyspareunia in a human subject comprising:

intravaginally administering estradiol to the subject by manually inserting about two inches into the vagina a liquid pharmaceutical composition comprising about 4  $\mu$ g to about 25  $\mu$ g of estradiol, wherein the composition has a viscosity from about 50 cP to about 1000 cP at 25° C., wherein the composition comprises all of the estradiol and is encapsulated in a capsule, and wherein the composition is inserted while the subject is in a reclining position or in a standing position;

wherein administration of the composition results in a decrease in the severity of moderate to severe dyspareunia in the subject within two to six weeks from the first administration.

2. The method of claim 1, wherein the method further comprises instructing the subject that once the composition has been administered, the subject may be ambulatory.

3. The method of claim 1, wherein the capsule is a soft gelatin capsule.

4. The method of claim 1, wherein administration of the composition results in an increase in the percentage of vaginal superficial cells within two weeks from the first administration.

5. The method of claim 1, wherein administration of the composition results in a decrease in the percentage of vaginal parabasal cells within two weeks from the first administration.

6. The method of claim 1, wherein administration of the composition results in a decrease in vaginal pH within two weeks from the first administration.

7. The method of claim 1, wherein the administration comprises inserting the composition once daily for two weeks and twice weekly thereafter.

8. The method of claim 1, wherein the moderate to severe dyspareunia is due to menopause.

9. The method of claim 1, wherein the composition contains 4  $\mu$ g estradiol or 10  $\mu$ g estradiol.

10. The method of claim 1, wherein the viscosity of the composition is from about 50 cP to about 380 cP at 25° C.

\* \* \* \* \*